

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicant: Glynne Ivo GUT et al.

Title: METHOD FOR DETECTION OF  
MUTATIONS IN DNA

Appl. No.: 10/563,090

Filing Date: 12/30/2005

Examiner: Unassigned

Art Unit: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

The references are discussed in the specification. English equivalents are provided for the foreign language references (B10 = B1; B11 = B4).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date MAR 21 2006

By *Stephen B. Maebius*

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/563,090
Date Submitted: MAR 21 2006 (use as many sheets as necessary)				Filing Date	12/30/2005
				First Named Inventor	Glynne Ivo GUT
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	1	of	2	Attorney Docket Number	065691-0428

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
B1	2002/0187493	A1	KOSTRZEWA et al.	12/12/2002		
B2	5,217,863	A	COTTON et al.	06/08/1993		
B3	5,830,655	A	MONFORTE et al.	11/03/1998		
B4	5,919,917	A	SHIONO et al.	07/06/1999		
B5	5,939,292	A	GELFAND et al.	08/17/1999		
B6	6,043,031	A	KOSTER et al.	03/28/2000		
B7	6,294,659	B1	PIRRUNG et al.	09/25/2001		
B8	6,468,748	B1	MONFORTE et al.	10/22/2002		
B9	6,566,055	B1	MONFORTE et al.	05/20/2003		

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
B10	DE	10108453		A1	Bruker Saxonia Analytik GmbH	09/12/2002	= B1	
B11	EP	0855403		A1	Laboratory of Molecular Biophotonics	07/29/1998	= B4	

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
B12		ASTATKE et al., "A single side chain prevents <i>Escherichia coli</i> DNA polymerase I (Klenow fragment) from incorporating ribonucleotides," Proc. Natl. Acad. Sci. USA, March 1998, Vol. 95, pp. 3402-3407.	
B13		CHANG et al., "Detection of ΔF508 Mutation of the Cystic Fibrosis Gene by Matrix-assisted Laser Desorption/Ionization Mass Spectrometry," Rapid Communications in Mass Spectrometry, 1995, Vol. 9, pp. 772-774.	
B14		FEI et al., "MALDI-TOF mass spectrometric typing of single nucleotide polymorphisms with mass-tagged ddNTPs," Nucleic Acids Research, 1998, Vol. 26, No. 11, pp. 2827-2828.	
B15		GRIFFIN et al., "Genetic analysis by peptide nucleic acid affinity MALDI-TOF mass spectrometry," Nature Biotechnology, December 1997, Vol. 15, pp. 1368-1372.	
B16		HAFF et al., "Single-Nucleotide Polymorphism Identification Assays Using a Thermostable DNA Polymerase and Delayed Extraction MALDI-TOF Mass Spectrometry," Genome Research, 1997, Vol. 7, pp. 378-388.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: <u>MAR 21 2006</u> <i>(use as many sheets as necessary)</i>				Application Number	10/563,090
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				Examiner Name	Unassigned
				Attorney Docket Number	065691-0428

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	B17	HAHNER et al., "Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry (MALDI) of endonuclease digests of RNA," Nucleic Acids Research, 1997, Vol. 25, No. 10, pp. 1957-1964.	
	B18	KARAS et al., "Laser Desorption Ionization of Proteins with Molecular Masses Exceeding 10000 Daltons," Anal. Chem., 1988, Vol. 60, pp. 2299-2301.	
	B19	KREBS et al., "RNaseCut: a MALDI mass spectrometry-based method for SNP discovery," Nucleic Acids Research, 2003, Vol. 31, No. 7, e37, 8 pgs.	
	B20	LITTLE et al., "Detection of RET proto-oncogene codon 634 mutations using mass spectrometry," J. Mol. Med., 1997, Vol. 75, pp. 745-750.	
	B21	LIU et al., "Rapid Screening of Genetic Polymorphisms Using Buccal Cell DNA with Detection by Matrix-assisted Laser Desorption/Ionization Mass Spectrometry," Rapid Communications in Mass Spectrometry, 1995, Vol. 9, pp. 735-743.	
	B22	RODI et al., "A Strategy for the Rapid Discovery of Disease Markers Using the MassARRAY™ System," BioTechniques, 2002, Vol. 32, pp. 62-69.	
	B23	ROSS et al., "High level multiplex genotyping by MALDI-TOF mass spectrometry," Nature Biotechnology, December 1998, Vol. 16, pp. 1347-1351.	
	B24	ROSS et al., "Discrimination of Single-Nucleotide Polymorphisms in Human DNA Using Peptide Nucleic Acid Probes Detected by MALDI-TOF Mass Spectrometry," Anal. Chem., 1997, Vol. 69, pp. 4197-4202.	
	B25	SAUER et al., "Genotyping single-nucleotide polymorphisms by matrix-assisted laser-desorption/ionization time-of-flight mass spectrometry," Journal of Chromatography B, 2002, Vol. 782, pp. 73-87.	
	B26	TOST et al., "Genotyping single nucleotide polymorphisms by mass spectrometry," Mass Spectrometry Reviews, 2002, Vol. 21, pp. 388-418.	

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